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Date: September 21, 2000, 2001 GROUP 1600, Art Unit 1623

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To: Ms. Deborah L. Cadena (Attny./Agent)

P-PM 3474 || 09/288,344 (Attny Docket No./Application No.)

Campbell & Flores LLP (Organization/Firm/Agency)

9-1-858-597-1585 (FAX/Telecopier Number)

From: Examiner L. E. Crane, Art Unit 1623.

Art Unit 1600's FAX machine may be accessed at (703) 308-4556.

Examiner's Office Phone No.: (703) 308-4639. If you have not received all pages of this transmission, please contact the Examiner at the above telephone number.

All FAX machines will be available to receive transmissions 24 hours/day, 7 days/week.

If you have not received all pages of this transmission and cannot reach the Examiner, please contact this Office as soon as possible at one of the following telephone numbers:

The Examiner's supervisor, Mr. Gary Geist, may be reached at (703) 308-1701.

The Group 1600 receptionist may be reached at (703) 308-1235.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE'S STAMPED DATE FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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DISCLAIMER: The following is submitted by FAX as an informal communication sent to applicant for the purpose of assisting in the negotiation of allowable subject matter. Applicant(s) is/are respectfully requested to reply at their earliest convenience by telephone to Exmnr. Crane at 703-308-4639 to advise examiner as to whether the instant suggested amendment is appropriate.

Parenthetical explanations following some proposed amendments will be deleted in any official examiner's amendment.

Upon reconsideration, the term "a host in need thereof" was not proposed because in every independent claim applicant identifies the "subject" of the treatment.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

In claim 1, at line 7, the term "a" was deleted in favor of the term -- the --.

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In claim 1, at lines 9 and 13, the term "a" (first occurrence) was deleted in favor of the term -- the --.

In claim 1, at lines 9-10 and 13-14, the term "a level corresponding to" was deleted. (Superfluous terminology.)

5 In claim 7, at lines 6, 9, 12 and 13, the term "a" was deleted in favor of the term -- the --.

In claim 7 at lines 6, 9, 12 and 13, the term "a" was deleted in favor of the term -- the --.

10 In claim 7 at lines 16-18, the term beginning ", thereby reducing ..." and the two following lines were deleted. (Repeats the preamble.)

In claim 19 at lines 6, 9, 12, 16 and 21, the term "a" was deleted in favor of the term -- the --.

In claim 19 at line 15, the entire line was deleted. (Repeats the preamble)

15 In claim 19 at lines 18-20 and lines 24-25, the term ", thereby reducing the toxicity ... gastrointestinal disorder" was deleted. (Repeats the preamble)

In claim 30 at lines 5, 7 and 11, the term "a" was deleted in favor of the term -- the --.

20 In claim 35 at lines 6, 9, 12 and 16, the term "a" was deleted in favor of the term -- the --.

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In claim 35 at line 15, the “thereby increasing therapeutic efficacy,” was deleted. (Repeats the preamble)

In claim 35 at lines 20-22, the term “, thereby reducing the toxicity ... gastrointestinal disorder” was deleted. (Repeats the preamble)

5 Claims 52-54 were cancelled without prejudice. (The term “non-IBD autoimmune disease” is a negative limitation which fails to identify the specific disease condition(s) being treated.)

In claim 55 at lines 9, 11 and 15, the term “a” was deleted in favor of the term -- the --.

10 In claim 55 at line 14, the “thereby increasing therapeutic efficacy,” was deleted. (Repeats the preamble)

In claim 55 at lines 17-19, the term “, thereby reducing the toxicity ... gastrointestinal disorder” was deleted. (Repeats the preamble)

15 In claim 64 at lines 4, 9 and 13, the term “a” was deleted in favor of the term -- the --.

In claim 64 at line 12, the “thereby increasing therapeutic efficacy,” was deleted. (Repeats the preamble)

In claim 64 at lines 17-19, the term “, thereby reducing the toxicity ... gastrointestinal disorder” was deleted. (Repeats the preamble)

20 Authorization for this Examiner’s Amendment was given in a telephone interview with Ms. Deborah L. Cadena on September [], 2001.

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The following is an Examiner's Statement of Reasons for Allowance:

Applicant's argument for the instant method of treatment claims which provide for adjustment of levels of drug administration as a function of internal concentrations of metabolites is particularly well supported by the **Belaiche et al.** (PTO-892 ref. W; applicant's "Exhibit 2") in the paragraph bridging pages 72 and 73 wherein the level of azathioprine had to be adjusted in two patients to avoid toxicity and to maintain efficacy, respectively.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number for the FAX machine now operated by Group 1600 is (703) **308-4556**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached on (703)-308-1701.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec
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